

§ 14.29

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of any other information not exempt from public disclosure under 5 U.S.C. 552b(c); the formulation of advice and recommendations to FDA on matters that do not independently justify closing.

(5) No portion of a meeting devoted to matters other than those designated in paragraph (b) (1) through (3) of this section may be closed.

(6) A matter which is properly considered in an open portion of a meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise the matters to be discussed in the closed portion.

(c) Attendance at a closed portion of a meeting is governed by the following rules:

(1) A portion of a meeting closed for the presentation or discussion of information that constitutes a trade secret or confidential commercial or financial information as defined in §20.61 may be attended only by voting advisory committee members, nonvoting members representing consumer interests who are also special government employees as provided in §14.80(b), the executive secretary of the advisory committee, a transcriber, consultants, and such other regular employees of FDA (including members of the Office of the Chief Counsel) as the chairman of the advisory committee may invite, and by those persons authorized to be present under §14.25(c), for presentation of information prohibited from public disclosure. A person making a presentation described in §14.25(c) may be accompanied by a reasonable number of employees, consultants, or other persons in a commercial arrangement within the meaning of §20.81(a).

(2) A portion of a meeting that has been closed for consideration of existing internal agency documents falling within §20.62 where premature disclosure is likely to significantly impede proposed agency action; personnel, medical, and similar files, disclosure of which would be a clearly unwarranted invasion of personal privacy within the meaning of §20.63; or investigatory records compiled for law enforcement

purposes as defined in §20.64 may be attended only by committee members (voting and nonvoting), the executive secretary of the committee, a transcriber, and other regular employees of FDA (including members of the Office of the Chief Counsel) whom the chairman of the committee may invite. Consultants, individuals performing personal service contracts, employees of other Federal agencies, and the general public may not attend such portions.

(3) If a person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section attempts to attend a closed portion of a meeting without the approval of the executive secretary and the chairman, and the matter is brought to their attention, the person will be required to leave the meeting immediately. This inadvertent and unauthorized attendance does not enable other unauthorized persons to attend, nor does it, of itself, constitute grounds for release of transcripts of closed portions or any other documents otherwise exempt from disclosure under §14.75 and part 20.

(4) If a person other than a person permitted to attend in accordance with paragraphs (c) (1) and (2) of this section is allowed by the executive secretary and the chairman to attend a closed portion of a meeting, that portion is open to attendance by any interested person.

[44 FR 22351, Apr. 13, 1979, as amended at 65 FR 56479, Sept. 19, 2000]

§ 14.29 Conduct of a hearing before an advisory committee.

(a) For each meeting, the open portion for public participation, which constitutes a public hearing under §14.25(a), will be at least 1 hour, unless public participation does not last that long, and may last for whatever longer time the committee chairman determines will facilitate the work of the committee. The FEDERAL REGISTER notice published under §14.20 will designate the time specifically reserved for the hearing, which is ordinarily the first portion of the meeting. Further public participation in any open portion of the meeting under §14.25(b) is solely at the discretion of the chairman.

(b) An interested person who wishes to be assured of the right to make an oral presentation at a meeting shall inform the executive secretary or other designated agency employee, orally or in writing, before the meeting.

(1) The person shall state the general nature of the presentation and the approximate time desired. Whenever possible, all written information to be discussed by that person at the meeting should be furnished in advance to the executive secretary or other designated agency employee. This material may be distributed or mailed by FDA to the committee members in advance of the meeting if time permits, and otherwise will be distributed to the members when they arrive for the meeting. The mailing or distribution may be undertaken only by FDA unless FDA grants permission to a person to mail or distribute the material.

(2) Before the meeting, the executive secretary or other designated agency employee shall determine the amount of time allocated to each person for oral presentation and the time that the presentation is to begin. Each person will be so informed in writing, if time permits, or by telephone. FDA may require persons with common interests to make joint presentations.

(c) The chairman of the committee shall preside at the meeting in accordance with § 14.30 and be accompanied by other committee members, who serve as a panel in conducting the hearing portion of the meeting.

(d) Each person may use the allotted time as desired, consistent with an orderly hearing. A person may be accompanied by additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 14.35(c).

(e) If a person is absent at the time specified for that person's presentation, the persons following will appear in order. An attempt will be made to hear the person at the conclusion of the hearing. Interested persons attending the hearing who did not request an opportunity to make an oral presentation may be given an opportunity to do so at the discretion of the chairman.

(f) The chairman and other members may question a person concerning that

person's presentation. No other person, however, may question the person. The chairman may allot additional time when it is in the public interest, but may not reduce the time allotted without consent of the person.

(g) Participants may question a committee member only with that member's permission and only about matters before the committee.

(h) The hearing is informal, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut matters presented. No participant may interrupt the presentation of another participant.

§ 14.30 Chairman of an advisory committee.

(a) The advisory committee chairman has the authority to conduct hearings and meetings, including the authority to adjourn a hearing or meeting if the chairman determines that adjournment is in the public interest, to discontinue discussion of a matter, to conclude the open portion of a meeting, or to take any other action to further a fair and expeditious hearing or meeting.

(b) If the chairman is not a full-time employee of FDA, the executive secretary or other designated agency employee, or alternate, is to be the *designated Federal employee* who is assigned to the advisory committee. The designated Federal employee is also authorized to adjourn a hearing or meeting if the employee determines adjournment to be in the public interest.

§ 14.31 Consultation by an advisory committee with other persons.

(a) A committee may confer with any person who may have information or views relevant to any matter pending before the committee.

(b) An interested person may submit to the committee a written request that it confer with specific persons about any matter pending before the committee. The request is to contain adequate justification. The committee may, in its discretion, grant the request.